K001989

JUL 2 5 2000

zimmer

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Summary of Safety and Effectiveness

Coonrad/Morrey Total Elbow

- **Submitted by:**

Zimmer, Inc.
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- **Prepared by:**

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- **Date:**

June 28, 2000

- **Trade Name:**

Coonrad/Morrey Total Elbow

- **Common Name:**

Elbow prosthesis

- **Classification Name:**

Prosthesis, Elbow, Constrained, Cemented

- **Substantial Equivalence Summary**

The modified Coonrad/Morrey Total Elbow is substantially equivalent to the unmodified Coonrad/Morrey Total Elbow, K973357, cleared March 2, 1998.

- **Device Description**

The modified Coonrad/Morrey Total Elbow is a total elbow prosthesis designed for use with acrylic cement and is available in regular, small, and extra-small sizes, in both left and right configurations. The ulnar component is curved to facilitate implantation and to establish the correct anatomical carrying angle. The anteverted hinge approximates the anatomical center of rotation and location to

minimize the reorientation of muscle forces and skin trauma. An articular design with 7° laxity tends to minimize the possibility of prosthetic rotation or loosening in the humerus or ulna. The anterior flange on the humeral stem accommodates a bone graft to enhance thickening of bone stock at the point where maximum stress on the elbow has been found to occur.

- **Intended Use**

  Indications include: post-traumatic lesions or bone loss contributing to elbow instability; ankylosed joints, especially in cases of bilateral ankylosis from causes other than sepsis; advanced rheumatoid or degenerative arthritis with incapacitating pain; revision arthroplasty, and instability or loss of motion when the degree of joint damage precludes less radical procedures.

  The candidate for total elbow arthroplasty should exhibit joint destruction which significantly compromises the activities of daily living. Patients with single joint involvement (generally those with traumatic or degenerative arthritis) or significant lower extremity disability which require walking aids are less amenable to treatment than patients with advanced and predominately upper extremity involvement. If possible, elbow replacement should be done after hip or knee surgery to avoid excessive stress to the prosthesis required by crutch walking during total hip or knee rehabilitation.

- **Performance Testing**

  Performance testing completed as part of the Design Control activities for the modified Coonrad/Morrey Total Elbow demonstrated that this device is safe and effective and substantially equivalent to the unmodified Coonrad/Morrey Total Elbow.

RA06004K.510

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 25 2000

Ms. Laura D. Williams
Regulatory Affairs Associate
Zimmer
P.O. Box 708
Warsaw, Indiana 46581-0708

Re: K001989
Trade Name: Coonrad/Morrey Total Elbow
Regulatory Class: II
Product Code: JDC
Dated: June 28, 2000
Received: June 29, 2000

Dear Ms. Williams:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exhibit B

510(k) Number (if known K001989

Device Name:

Coonrad/Morrey Total Elbow

Indications for Use:

Indications include: post-traumatic lesions or bone loss contributing to elbow instability; ankylosed joints, especially in cases of bilateral ankylosis from causes other than sepsis; advanced rheumatoid or degenerative arthritis with incapacitating pain; revision arthroplasty, and instability or loss of motion when the degree of joint damage precludes less radical procedures.

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use
(Per 21 CFR 801.109) (Optional Format 1-2-96)

RA06004K.510

Donna R. Wichmen
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K001989